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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/780,843	02/09/2001	Charles F. Milo	1849.16102B-CIP	8513
26308	7590	01/12/2005	EXAMINER	
RYAN KROMHOLZ & MANION, S.C. POST OFFICE BOX 26618 MILWAUKEE, WI 53226			NGUYEN, VI X	
			ART UNIT	PAPER NUMBER
			3731	

DATE MAILED: 01/12/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/780,843

Applicant(s)

MILO ET AL. *CM*

Examiner

Victor X Nguyen

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 October 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8, 33 and 34 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 33 is/are allowed.
- 6) ☒ Claim(s) 1-8 and 34 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1 –8 and 34 are rejected under 35 U.S.C. 102 (e) as being anticipated by Epstein et al (U.S. 5,782,860).

Epstein et al disclose in Figs. 1,3-4 and 5c, a system for percutaneously forming a closure material to seal a puncture in the tissue of human body having the limitations of claims 1-2,7-8 and 34, including: the closure material comprises a mixture components which, upon mixing, react to form a solid closure material composition (see col. 5, lines 22-32), where a catheter (22) has a distal end, and at least one nozzle (28) locates adjacent the distal end. A structure (32) comprises a wall which defines an interior and exterior of the structure. Item 32 of Epstein comprises an open configuration which is capable for allowing blood to flow through the wall of the structure, and where the closure material composition forms a localized in situ which is adjacent the vessel puncture site to seal the vessel puncture site (see col. 5, lines 21-47). Note that an introducer assembly (86,87) is capable of dispensing a mixture components into the catheter lumen, and where the introducer assembly includes a mixing chamber (91) to bring the mixture components into a mixed condition before entering the catheter lumen (see col. 5, lines 34-49). Furthermore, at best seen of fig. 3, item 36 of Epstein can be broadly characterized as a

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closure composition test chamber. Note: The introductory statement of intended use and all other functional statements have been carefully considered but are deemed not to impose any structural limitations on the claims distinguishable over the Epstein et al reference which is capable of being used as claimed if one desires to do so.

Regarding claims 3 and 4, where the assembly further includes a mechanism to operate the structure (32) between a collapsed and an expanded condition; and wherein the mechanism includes an element (47- inherent feature) to lock the structure in a desired condition.

Regarding claims 5 and 6, where an introducer assembly (86,87) communicates with the catheter; and wherein the introducer assembly includes an air vent (28).

Allowable Subject Matter

2. Claim 33 is allowed.

The following is a statement of reasons for allowance: None of the prior art of record, alone or in combination, discloses or suggests where an introducer assembly communicates with the catheter lumen for dispensing the first and second components into the catheter lumen, where the introducer assembly includes a mixing chamber which includes an interior mixing structure to bring the first and second components into a mixed condition before entering the catheter lumen, and where a structure is carried by the catheter distal to the at least one nozzle and is arranged for expansion within the blood vessel to resist outward passage through the puncture site and to locate the at least one nozzle outside the blood vessel adjacent the puncture site.

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As allowable subject matter has been indicated, applicant's reply must either comply with all formal requirements or specifically traverse each requirement not complied with. See 37 CFR 1.111(b) and MPEP § 707.07(a).

Response to Arguments

3. Applicant's arguments filed 10/25/2004 have been fully considered but they are not persuasive. With respect to claim 1, the examiner disagrees with applicants' remarks that the device of Epstein does not teach a structure comprising an open configuration allowing blood flow through the structure. As the examiner has pointed out above, a structure (32) comprises a wall which defines an interior and exterior of the structure. Item 32 of Epstein can be characterized as a broadly structure that includes an open configuration which is capable for allowing blood to flow through the wall of the structure. Furthermore, regarding the introductory statement of intended use "the structure comprises an open configuration allowing blood flow through the wall of the structure" has been carefully considered but are deemed not to impose any structural limitations on the claims distinguishable over the device of Epstein which is capable of being used as claimed if one desires to do so. Therefore, the invention as claimed has not been structurally defined over the device of Epstein.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Victor X Nguyen whose telephone number is (571) 272-4699. The examiner can normally be reached on M-F (8-4.30 P.M).

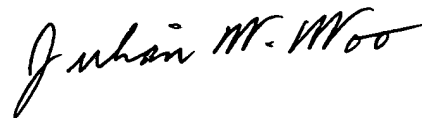
The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Victor X Nguyen
Examiner
Art Unit 3731

Vn *✓*
1/7/2005



JULIAN W. WOO
PRIMARY EXAMINER